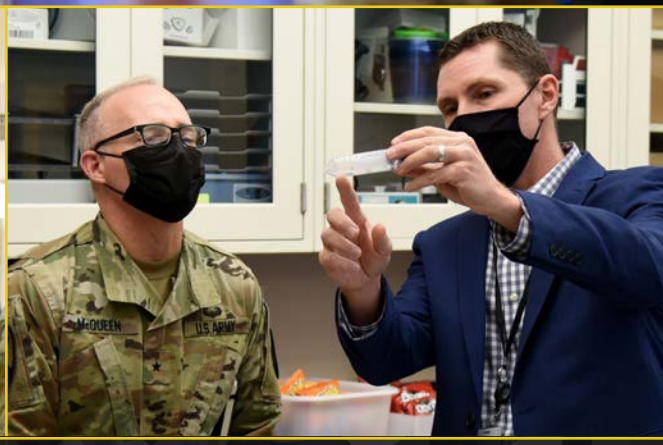
UNITED STATES ARMY

INSTITUTE OF SURGICAL RESEARCH



2021 | YEAR IN REVIEW

U.S. Army Institute of Surgical Research

2021 Year in Review

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Col. Mark E. Stackle, MD

USAISR Senior Enlisted Leader
SGM Larry D. White II

From the desk of the USAISR Commander

The year 2021 was another exceptional year full of change for the U.S. Army Institute of Surgical Research. First of all, SGM Jennifer Francis departed in April for her next duty station at the U.S. Army Medical Command, and we welcomed SGM Larry White as the institute's newest Senior Enlisted Leader. SGM White's experience, leadership, and mentoring have been a tremendous asset to the ISR since his arrival.

While the pandemic saw much of our critical combat casualty care research come to a halt in 2020, we were able to slowly and deliberately ramp up our critical research efforts in 2021. Throughout the year, the Research Directorate continued to refine the new organizational structure focused on the physiologic challenges of combat casualty care research. You can see a graphic on Page 8 which outlines the 5+1 Pillars approach we have taken to address the most critical capability gaps in battlefield medicine. This approach has already garnered tremendous interest from across the medical research enterprise, and has us well positioned to continue delivering innovative solutions to the most pressing challenges.

One of the areas that has remained constant during 2021 is the hard work and dedication to patient care shown by our staff within the ISR Burn Center. The Burn Center team has continued their tremendous work of caring for patients suffering from burn injuries from across the DOD and South Texas. In addition, our team has demonstrated outstanding agility as they also assumed the care for numerous critically ill COVID patients in the Burn Center. Members of the Burn Flight Team also flexed beyond their typical duties and assisted in the ground and aerial transport of multiple severely ill COVID patients. The Burn Flight Team also continued to send members to the Air Force's Critical Care Air Transport Team training courses ensuring that the Team is fully qualified to integrate seamlessly with our Joint partners during any contingency operation.

The ISR also contributed to the local Joint Base San Antonio COVID response mission. Several ISR Soldiers floated to the Fort Sam Houston vaccination site while many of our 68Ks (Medical Laboratory Specialists) supported the Brooke Army Medical Center COVID testing site as the delta and omicron variants surged. As always, our Soldiers performed their duties admirably, making us all proud of their support in fighting this deadly virus.

As we shift our focus to 2022 and beyond, I continue to be proud of the exceptional work that takes place within this institute. As we continue to drive innovation in combat casualty care research and provide world class health care within the Burn Center, it is clear to me that we are blessed with a team of committed professionals. I hope this "Year in Review" issue provides you a glimpse of the ISR Team's steadfast devotion to our mission and our ongoing commitment to Optimize Combat Casualty Care!

Forge the Future!

Col. Mark E. Stackle, MD, USA
USAISR Commander

SGM Larry D. White III, USA
USAISR Senior Enlisted Leader

Mission

Optimize Combat Casualty Care

Vision

The world's premier research organization delivering transformative advances in combat casualty care.

OPERATIONALLY Responsive Clinical Research

Operationally Relevant Laboratory Research

Rapid Clinical Translation

Combat Casualty and Burn Research

Development of Military Clinicians & Researchers

Operational Experience

Clinical Care and Research

The guiding strategy for the Institute's research program is to take the clinical problems identified on the battlefield into the research laboratory for further investigation and the development of solutions and then to validate those solutions in the clinical setting before they are returned to the battlefield as medical doctrine.

USAISR At a Glance

The USAISR is a worldwide leader in combat casualty care research, producing medical devices, biomedical research and novel therapeutics to treat Warfighters from the point of injury through the continuum of care.

- One of seven research institutes under the U.S. Army Medical Research and Development Command of U.S. Army Futures Command.
- Conducts requirements-driven, programmatic research to develop knowledge and materiel products that drive evidence-based, best clinical practice solutions and deliver advanced technologies for the Warfighter.
- Provides state-of-the-art burn, trauma, and critical care to DOD beneficiaries worldwide and civilians throughout the South Texas region.
- Deploys critical-care Burn Flight Teams worldwide to perform aeromedical evacuation.
- Premiere translational research center focusing on trauma, burns, and critical care of the combat wounded—able to take clinical problems to the laboratory and translate laboratory advances to the clinic, operating room, or battlefield.

Accomplishments

Finalized Development of the New Tablet-Based and Mobile-Based Burn Navigator

- To support the Air Force Critical Care Air Transport Teams and Army deployed clinical teams that provide care for acute burn combat casualties.
- Deployed as an App and available for civilian burn providers in both the Android and Apple stores and military providers in the Defense Information Systems Agency app store.

Characterization of the Automated Critical Care System Fluid (ACCS) Infusion Module

- To support development of new fluid resuscitation algorithms for automated transport and evacuation of combat casualties.
- Took over development of the ACCS platform from the Office of Naval Research.
- Continued funding the development of the system to support various automation capabilities for combat casualties.

Developed Several Augmented Reality (AR) Applications for Use on the Microsoft HoloLens

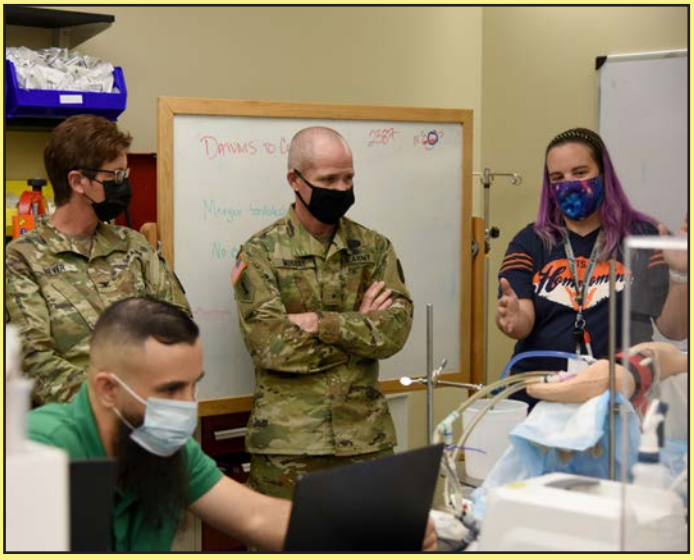
- To support the Medical Simulation and Information Science Research Program Virtual Health program focused on development of technologies that can be used in Multi-Domain Operations environments with limited or no connectivity**.**
- To test advanced AR in a field environment for the care of a severely burned combat casualty requiring multiple critical care interventions.
- Applications included an automated burn estimation system, an electronic application for displaying the Joint Trauma System clinical practice guidelines, application for supporting burn resuscitation, pain management, sedation, drug calculations, and escharotomy guidance.

Developed Clinical Decision Support System Based on Converted Clinical Practice Guidelines

- To provide users at the point of injury with an intelligent assistant that provides clinical decision support capabilities based on the standard of care guidelines.
- Uses a C Language Integrated Production System to implement rules stored as a knowledge base encompassing current standard of care for several injury types.

Finalized and Tested the Initial Iteration of the Burn Patient Transfer System

- In collaboration with Telemedicine and Advanced Technology Research Center, Chenega, and St. Barnabas Medical Center.
- Designed to manage burn patients in a mass casualty environment.
- To provide a national military/civilian emergency management system for burn patients.
- Full deployment expected next year.

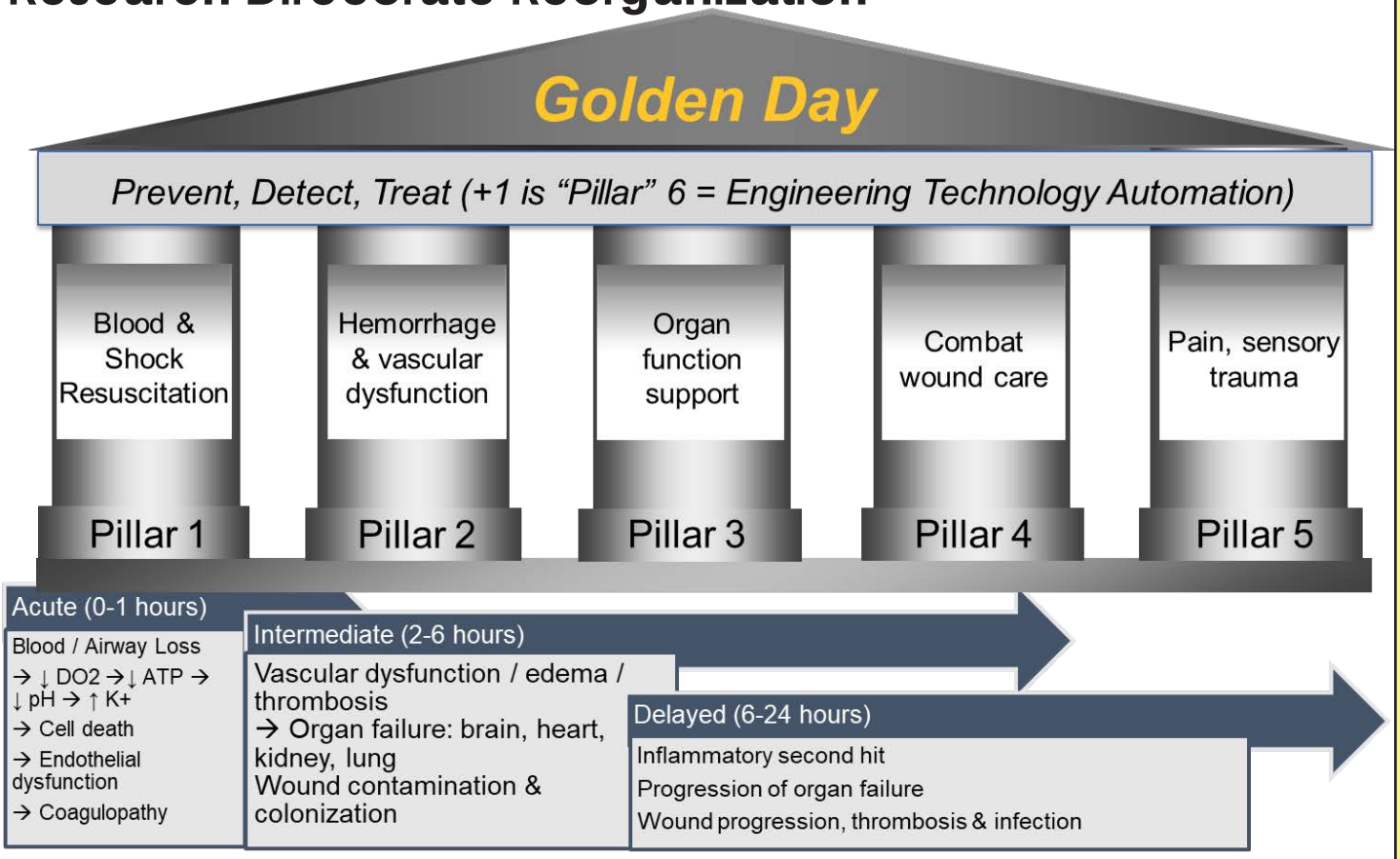


8 of 10 Top Contributing Authors to the Scientific Literature on Combat Casualty Care are from ISR

High-impact contributions to the combat casualty care literature

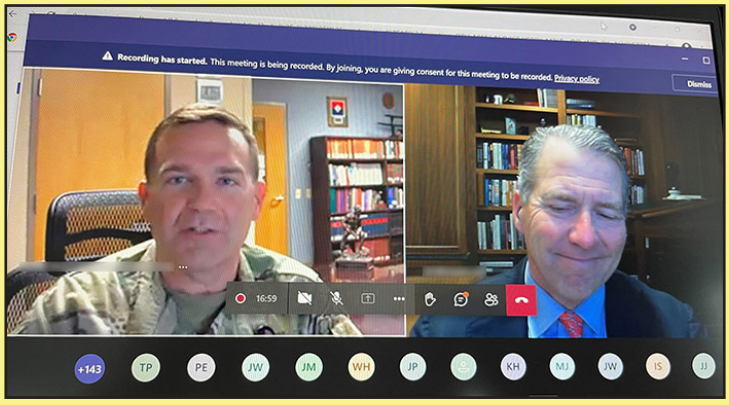
- For more than two decades, some of ISR's most noteworthy contributions to combat casualty care research have redefined hemorrhage control, resuscitation, combat transfusion medicine, burn care, trauma physiology, wound infection management, and trauma and reconstructive surgery.
- Annual supplements dedicated specifically to combat casualty care in order to further highlight these scientific discoveries for translation to clinical use.
- ISR current and former staff have submitted 1,768 manuscripts from 2001-2021.
- ISR research has informed numerous Joint Trauma System and other Clinical Practice Guidelines.

Research Direcorate Reorganization



- The USAISR's '5+1' Pillar Model organizes around the physiology of trauma.
- Focuses on a team approach and transformational advances.
- Goal of transforming combat casualty care in future conflicts like we have over the past 20 years.

ISR Hosts a Medical Science, Technology Innovation Virtual Summit



- To foster increased collaboration in the arena of combat casualty care research and to strengthen the relationship between Army Futures Command and the University of Texas System (UT System).
- More than 200 participants from AFC, MRDC, and the various institutions within the UT System.
- Key deliverables included the establishment of an Educational Partnership Agreement (EPA) and Cooperative Research and Development Agreement (CRADA) between ISR and UT System. These documents were signed in January 2022 and are currently in effect.
- The CRADA allows for more streamlined collaboration between USAISR and UT System institutions in the area of trauma and combat casualty care.
- The EPA will make it easier for the USAISR and UT System institutions to engage in educational engagements between organizations that will have benefit for all involved.

Burn Center

- Principal mission is to conduct research and development to improve the clinical care of burn patients.
- Vision is to be the Nation's leader in the multidisciplinary care of, and translational research for, severly burned combat casualties and those with similar injuries.
- As America's Burn Center, we serve the Warfighter and the people of Texas.
- The multidiscplinary team of healthcare professional is highly experienced in burn care.
  - Burn Intensive Care Unit beds: 16
  - Operating Rooms: 2
  - Progressive Care Unit beds: 24
  - Rehabilitation Gyms: 2

577 total admissions in 2021

Burn Intensive Care Unit admissions:	242
Progressive Care Unit admissions:	335

Army Burn Flight Team

- Home of the Army Burn Flight Team comprised of qualified, specially trained personnel.
- The Team has conducted nearly 100 overseas missions since 2003.
- Ready to deploy world-wide within 12 hours for both military and civilian patients in order for the patient to receive specialty burn care while in flight.

Burn Flight Team used to transport COVID-19 patients:
Burn Flight Team members were involved in transporting 36 COVID patients to the Burn Center and Brooke Army Medical Center. Three of those patients were transported into San Antonio by air and the other 33 via ground. Most of these patients were transported from within Texas, but three patients were transported from Kuwait, Germany and Alsaska.

Burn Flight Team Members continued to attend the U.S Air Force Critical Care Air Transport Team (CCATT) Initial and Advanced courses. Nine members completed the Initial course and four completed the Advanced course. Future attendance and participation in CCATT training will ensure interoperability with the USAF CCATTs, and Burn Flight Team mission readiness.

Burn Center cont.

Clinical Education Branch focused on expanding course offerings and increasing participation in the Clinical Pre-Deployment Training initiative. Also, in conjunction with the Research Directorate, Clinical Education continued researching the efficacy of the program.

Pre-Deployment Readiness Training is a two-week course available to teams of service members who are preparing for deployment. This training includes introduction to burn management with a focus on teambuilding, Advance Burn Life Support (ABLS) Certification (if available), hands-on training with skilled Burn Center staff and high-fidelity simulation training. The program had a decrease in the number of teams participating due to the pandemic. Nonetheless, 69 team members from 7 teams trained 320 hours before deploying.

Clinical Burn Symposium is offered quarterly. The two-day symposium consists of lectures given by subject-matter experts from across the Burn Center. The Burn Symposium afforded attendees the opportunity to enhance knowledge about assessment, management and treatment modalities for burn patients. The lectures also introduced current clinical practice guidelines that impact care delivery. The Burn Symposium provided information that can immediately be applicable to all aspects of burn care for the novice or experienced healthcare provider. Three symposiums were conducted for 128 attendees issuing 64 continuing education hours.

Advanced Burn Life Support Provider Certification Program is an eight-hour course for physicians, nurses, physician assistants, nurse practitioners, therapists, and paramedics. This live, hands-on training provides the "how-to" of emergency care for a burn patient through the critical first 24 hours post injury. Ten classes were held for 172 attendees earning 90 continuing education hours.

Clinical Rotation Program allows non-physician students to apply knowledge from the classroom to real-life medical situations. During rotations, students shadow members of the multidisciplinary team in the Burn Center and have access to patients, in order to gain valuable hands-on experience. A total of 15,807 clinical rotation hours were conducted at the Burn Intensive Care Unit, the Progressive Care Unit, the Post Operative Nursing Service, the Rehabilitation Department, and the Respiratory Therapy Department.

In support of the Defense Medical Readiness Training Institute and Brooke Army Medical Center, the Clinical Education Branch provides the **Trauma Nursing Core Course** (TNCC). TNCC delivers the knowledge, critical thinking skills and hands-on training needed to keep trauma patients safe. The course objective is to improve trauma patient outcomes by providing nurses with foundational trauma knowledge, skills, and a systematic Trauma Nursing Process to guide trauma patient care. A total of 290 hours were conducted on the TNCC.

The Clinical Education Branch augments the **Medic Utilization Program** (Medic UP) training for all Healthcare Specialists (68W) and Aerospace Medical Service Specialists (4N0) assigned to BAMC. This monthly training helps prepare 68Ws and 4N0s to manage burns in a prolonged field care environment. Due to COVID-19, no personnel attended Medic UP in 2021.

Continuing Education, to include Continuing Medical Education and Continuing Nursing Education, helps those in the different healthcare fields maintain competence and learn about new and developing areas of their field. The activities take place as live events, written publications, online programs, audio, video, or other electronic media. 80.75 CME and CNE hours were earned at six events.

Clinical Augmentation Program is on-the-job training of research and administrative nursing staff (augmentees). This included developing an on-boarding/training plan and standard operating procedure while maintaining force health protection. A total of 900 augmented clinical nursing care hours were conducted at the BICU, 4 East, and PACU clinical departments.

Burn Center cont.

Behavioral Health Study Branch

- To improve return-to-duty rates and community reintegration.
- Serves as a specialty consultation service in the Burn Intensive Care Unit.
- Patients are either assessed and/or screened for behavioral health ailments that may impede psychological outcomes after burn injury.
- Responsible for the national partnership with the Phoenix Society Survivors Offering Assistance in Recovery Peer-Support (SOAR) Program.
    - SOAR Program consists of four modules: Group, Individual, Staff and Community Care. survivors who had developed post traumatic growth.
    - Conducted 8 Group, 5 Staff, and 2 Community Care events.

Burn Clinical Pharmacy Service

- Provided medication screening, assessment, and therapeutic drug monitoring/pharmacokinetic interventions.
- Ensured medication is appropriate, effective, and timely.
- Represented pharmacologic aspect of burn care.
- Supports education by precepting student and resident pharmacists.
- Provided education to other Burn Center departments.
- Strived to advance the knowledge, understanding, and care of patients by serving on the Burn Center's Performance Improvement Council.

Clinical Research

- Staff worked throughout the year to support ISR's principal mission of conducting research and development to improve the clinical care of burn patients.
- Investigators met monthly to discuss project progress, provide education on research-related topics, and brainstorm ideas for future projects.
- Clinical burn fellows are required to participate in research to complete the burn fellowship program.
- Staff particpated in 22 research protocols as either principal or associate investigators.
    - Nineteen studies were led by Burn Center personnel.

Burn Strong is the Burn Center's Outreach Program to the South Texas civilian community. It began as a partnership between the Burn Center and the San Antonio Fire Department in 2019, to help paramedics and emergency medical technicians learn the basics of advanced burn and trauma life support care.

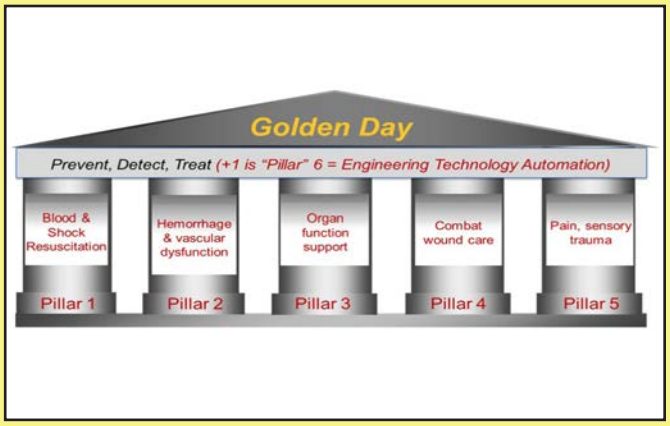
Burn Strong expanded the program to provide classes in the Southwest Texas Regional Advisory Council area and also provides burn injury prevention awareness activities at San Antonio special events.

A total of 49 Burn Strong Outreach classes were conducted for 1,096 paramedics, emergency medical technicians and health care providers and 5 Burn Strong Injury and Prevention activities were conducted in San Antonio for 450 community members.

BURN STRONG

Research Directorate

The Research Directorate re-organized into physiological based Pillars (5+1). The goal was to create integrated, cross-functional Combat Casualty Care Research Teams (CRTs) with co-leads (Science Leads and Program Managers). These positions were supported by an administrator and operations and financial manager to improve RD's responsiveness to ever increasing quarterly reporting to higher Headquarters and achieve finer visibility down to the individual project.



CRT1: *Blood and Shock Resuscitation*

Focused on platelets, whole blood, anti-shock therapeutics, acute traumatic coagulopathy, and cell therapy to address acute and prolonged field care needs for combat casualty care.

Platelets

- Continued participation in multi-site study evaluating cold-stored platelets for up to 21 days across multiple collection platforms.
- Developed and refined a clot retraction assay for measuring platelet activity.
- Identified several metabolic changes in platelets as a function of storage that contradicts original understandings of platelet function.

Whole Blood

- Continued collaborations with the Armed Services Blood Program led to identification of operational challenges and unique logistical demands.
- Developed new blood storage and shipping devices.
- Evaluated drone delivery systems of whole blood.

Anti-Shock Therapeutic

- Continued positive results from evaluating novel pharmaceutics.
- Preclinical studies demonstrate significant improvements in survival compared to vehicle controls.
- Preliminary testing of the effectiveness of known shock drugs.

Acute Traumatic Coagulopathy

- Continued development and evaluation of dried blood product.
- Demonstrated healthy and recovering fibrinogen levels versus those with coagulopathy.
- Continued refinement of algorithm for automated parameterization of optical density in clot retraction assay.

Cell Therapy (mesenchymal stem cells, MSCs) for Immunomodulation in Trauma

- Studies in in-vitro whole blood model found a reduction in clot time.
- Storage-MSCs were found to remain viable and express metabolic activity when stored at 4°C for up to two week.
- Explored interactions between MSCs and key immune cells to develop potency assays.

Direct Translation of Research to Operations

- Freeze-dried and spray-dried plasmas from multiple sources were evaluated for resuscitation effectiveness in laboratory assays.
- Hemoglobin-based oxygen carriers (HBOCs) do not offer hemostatic function but may serve as bridges to transfusion in hemorrhagic shock.
- Low Titer Group O Whole Blood (LTOWB, cold stored, low anti-A an B titer) is now being provided at several installations.

Research Directorate cont.

CRT2: *Hemorrhage and Edema Control*

The mission of this CRT is to improve mortality and morbidity of combat casualties by controlling hemorrhage from bleeding wounds and edema formation following traumatic injury.

- Uncontrolled hemorrhage is the leading cause of potentially survivable deaths on the battlefield.
- Emphasis is on understanding the endotheliopathy and vascular leak that accompanies hemorrhage and other traumatic injuries.
- Demonstrated that spectral reflectance can still discriminate between tracheal and esophageal tissues despite the presence of bodily fluids or soot.
- Performed a clinical study on the efficacy of spectral reflectance to distinguish tracheal tissue in healthy humans and in burned patients.
- Demonstrated that analgesic doses of opioids do not significantly depress cardiorespiratory function or survival in a model of extremity trauma and hemorrhage.
- Developed a research model of rhabdomyolysis induced by prolonged tourniquet use which has relevance for Prolonged Field Care scenarios.

CRT3: *Organ Function Support*

The mission is to deliver materiel and knowledge products that enhance Soldier survival at the point of injury and during prolonged care outside of hospitals by focusing on the mitigation of organ dysfunction resulting from traumatic injury.

- Employed models of polytrauma to investigate safety and feasibility of various interventions to advance mobile and/or wearable critical care and life support devices far-forward.
- Made progress in evaluating technologies to support lung and renal replacement therapy needs on the battlefield.
- Made progress to define bioeffects of Extracorporeal Life Support (ECLS) alone and in combination with standard of care treatments during management of combat-relevant injuries over 72 hours.
- Made progress on developing antithrombotic strategies to support field deployable ECLS without heparin administration and mitigate low-flow associated clot formation.

CRT4: *Combat Wound Care*

Reorganized to merge three research areas: Burn and Wound Infection, Dental and Craniomaxillofacial Trauma, and Extremity Trauma.

Burn and Wound Infection

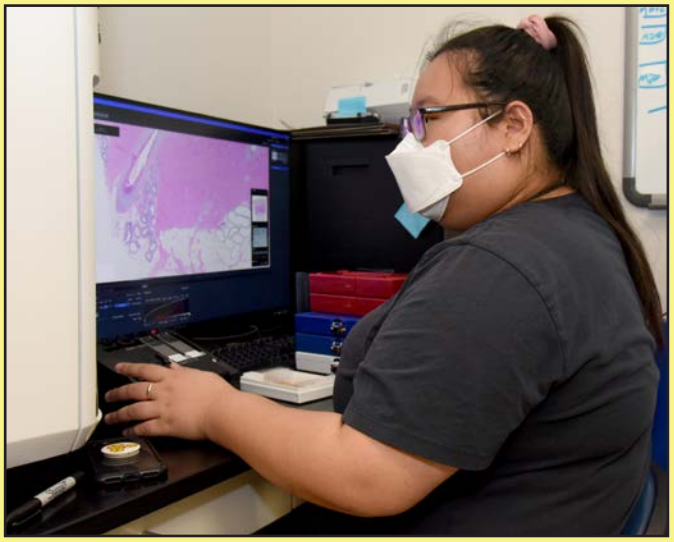
- Focused on new treatments to address the current gaps in burn injuries and wound infection on the battlefield.

Dental and Craniomaxillofacial Trauma

- Focused on developing solutions for trauma injuries to the head and face.

Extremity Trauma

- Focused on improving outcomes of extremity trauma with specific emphasis on preventing infection of complex wounds.
- Clinical trial evaluated very early administration of topical antibiotics in open fractures.



Research Directorate cont.

CRT5: *Battle Field Pain Management and Sensory Trauma*

To identify novel approaches for treating pain and repair/restore the sensory system from injuries sustained by Warfighters.

- Pain management focused to improve care to Warfighters at the point of injury through role 2.
- Continued developing Battlefield Analgesics to identifying novel pain management options that are effective, safe, and maintain Soldier lethality on the battlefield.
- Continued work on penetrating ocular Injury model and temporary cornea repair projects.
- New Advanced Blast Stimulator obtained and calibrated for ongoing projects related to pain and blast-induced sensory trauma.
- Preclinical battlefield pain and trauma models developed and approved.

CRT6: *Engineering, Technology & Automation*

The mission of CRT6 is to research and develop materiel solutions and concepts that utilize information and engineering technologies to improve outcomes of combat casualties from point of injury to Role of Care 3.

- Supported capability gaps associated with future Multi-Domain Operations, Large Scale Combat Operations, and Prolonged Care environments.
- Developed and maintained software development, engineering research, and advanced information technology concepts including medical Artificial Intelligence, Machine Learning, and automation technologies identified to support current and future medical operational environments.
- Finalized development of the new tablet-based and mobile based burn navigator system.
- Developed several Augmented Reality Applications for use on the Microsoft HoloLens System.
- Developed a clinical decision support system for use by medics using advanced rule-based engine based on converted clinical practice guidelines
- Patent for system and method for ultrasound imaging: method is a novel concept that uses a vibration control module to enhance ultrasound imaging clarity of ultrasound images and video.

Research Support Groups

Veterinary Support Group

- Support a 120,000 square foot space providing logistical and technical assistance for combat casualty care studies.
- Tasked with converting space to potentially receive COVID19 patients.
- Conversion can be implemented within three days for immediate patient care.
- Department of Defense lead laboratory for prolonged field care studies.

Clinical Research Support Department

- Nexus between the Burn and Research Directorate.
- Prospective and retrospective studies.
- Tasked with converting space to potentially receive COVID-19 patients.
- Supported Burn Center-specific performance improvement projects.

Pathology and Epidemiology/Biostatistics

- Anatomic Pathology Section processed 3,762 blocks of tissue and made 9,910 protocol slides supporting 54 protocols.
- Clinical Pathology Section processed 2,263 specimens for 49 protocols.
- Molecular Pathology Section performed 1,642 immunohistochemical stains, 346 TUNEL apoptosis stains, 8 immunohistochemical antigen optimizations, and 252 protein extractions for molecular pathology staining, supporting 25 protocols.
- Epidemiology and Biostatistics sections supported 36 protocols and five proposals, analyzed data for 28 projects, and coauthored 17 manuscripts and 11 abstracts.

Business Development/Office of Research and Technology Applications

- Executed 57 new agreements.
- Drafted agreements with the University of Texas System.
- Facilitated submission of two invention disclosures.
- Led a thorough analysis of nonprofit foundation supported extramural research.
- Coordinated all Army intramural research related taskers.

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